

REMARKS

The specification has been amended at pages 9 and 20 to delete embedded hyperlinks. Claims 2, 4, 12, 13, and 15 have been canceled without prejudice. Upon entry of the present amendment, claims 1, 3, 5-11, and 14 will be pending. No new matter has been added.

The following remarks are in response to the Office Action mailed January 30, 2009 (“the Office Action”).

Objection to the Specification

The Office Action objected to the specification for containing an embedded hyperlink at pages 9 and 20. This objection is overcome by the present amendment to delete the embedded hyperlinks.

Rejections under 35 U.S.C. § 112, first paragraph (enablement)

Claims 2, 4, 12, 13, and 15 were rejected as allegedly lacking enablement. The Office Action stated that the specification is enabling for lessening the severity of food allergies or anaphylactic shock, but does not reasonably provide enablement for prevention of food allergies or anaphylactic shock. The Office Action stated that “[i]n order to be enabled for prevention of a condition, applicant must demonstrate that the invention is able to prevent the condition in each and every instance of that condition.” It further stated that applicants’ specification does not show prevention of food allergies or anaphylactic shock.

To advance prosecution, applicants have canceled claims 2, 4, 12, 13, and 15 in the present amendment. Withdrawal of this rejection is respectfully requested.

The enablement of claims 1, 3, 5-11, and 14, which refer to compositions for treating or lessening the severity of food allergy or anaphylactic shock, has been acknowledged. For clarity, Applicants would like to note that these claims encompass compositions for, and methods of, treating and lessening the severity of food allergy or anaphylactic shock, in which a subject that has received the composition exhibits lessened (e.g., partially or completely reduced) symptoms of an allergic or anaphylactic reaction to an allergen. The specification discloses, *inter alia*, that the present herbal compositions can be used to treat existing allergic symptoms, to delay the onset of symptoms in an individual who has previously suffered allergic symptoms, or to reduce the severity, intensity, or duration of subsequently-developed symptoms (see the specification, e.g., paragraphs [0118]-[0120], at pages 28-29). The present compositions can be administered

prior to the onset of symptoms after a subsequent encounter with antigen, or prior to the encounter and/or prior to the development of allergic sensitivity to a particular antigen (see the specification, e.g., paragraphs [0119] and [0120] at pages 28-29). Such uses are exemplified in the specification. For example, Examples 1-3 describe experiments in which mice were sensitized and challenged with peanuts (PN) and cholera toxin. Prior to challenge, sensitized mice were treated with a formulation that falls within the present claims, FAHF-2. FAHF-2 was shown to block anaphylactic reactions, whereas 100% of sham-treated mice developed anaphylactic reactions (Example 3 and Figure 3). Experiments with manufactured FAHF-2 also showed that the herbal formulation blocked anaphylactic reactions (see Example 6 and Table 3). In addition, FAHF-2 was shown to prevent anaphylaxis five weeks after discontinuation of treatment (Example 7).

Rejections under 35 U.S.C. § 103

Claims 1-7 and 10-15 were rejected as allegedly unpatentable over WO 01/66122 (“Sampson”). The Office Action acknowledged that the ‘122 application does not specifically teach a single embodiment in which an herbal composition has the same ingredients as claimed. However, it alleged that “an artisan of ordinary skill would be motivated to select between the ingredients taught by Sampson because Sampson does not teach that all of the herbal ingredients are required.” That which the reference does *not* teach cannot serve as a basis for the rejection. Sampson does not disclose the specifically claimed compositions or methods of using them, and it does not provide any guidance indicating that the specifically claimed compositions would be effective to treat or lessen the severity of food allergy or anaphylactic shock. The requisite motivation to provide the specifically claimed compositions is not found in Sampson. *A prima facie* case of obviousness has not been established.

The Office Action further stated that “the reference specifically teaches that each of these ingredients is known to be useful in treating allergies.” Applicants do not see where the reference provides any such teaching as to the individual components. In fact, the efficacy of individual components of the composition have been examined in a mouse model of food allergy. These studies are described in the present application. See Example 8, Table 4, of the present specification, which shows that none of the individual components of the claimed herbal composition reduced anaphylaxis as potently as FAHF-2. In these experiments, 0% of mice treated with FAHF-2 exhibited anaphylactic reactions (n=14), whereas 60% or more of mice

treated with a single component exhibited anaphylactic reactions, with the exception of animals treated with Huang Bai, of which 25% were anaphylactic. Therefore, applicants disagree with the applicability of the conclusion in the Office Action that it would be “*prima facie* obvious to combine together two or more ingredients into a single composition when the prior art teaches that each of the individual ingredients is known to be useful for the same purpose.” Such teaching is not found in the cited reference and is not supported by applicants’ present data.

Traditional Chinese Medicinal formulations often rely on activity of multiple herbal components together. Certain herbal compositions shown to be effective in Sampson have eleven components. One would not have expected that compositions lacking multiple components would be effective. Consistent with this principle, Applicants have examined simplified preparations of the presently claimed compositions and found that they are far less effective. Applicants submit herewith a copy of a published article, Kattan et al. (*Phytother. Res.*, 22:651-659, 2008; copy attached as **Exhibit A**) in which efficacy of FAHF-2 was compared to a simplified formula having three components thought to be most effective individually. This simplified formula was called sFAHF and included *Phellodendron chinense*, *Ganoderma lucidum*, and *Zingiber officinalis*. When Kattan et al. examined protection from anaphylaxis due to challenge with peanut antigens in a mouse model, it was found that “sFAHF did not replicate the results observed in FAHF-2 treated mice where all animals in the group (4/4) were protected ($p < 0.01$)” (Kattan at page 656, right column). sFAHF also did not significantly reduce plasma histamine (an indicator of severity of an allergic reaction), and it reduced peanut antigen-stimulated cytokine release to a lesser extent than FAHF-2 (Kattan at page 657, left column and Figures 4 and 5). The authors concluded that FAHF-2 was more effective than individual components or than sFAHF, and that the components of FAHF-2 may work synergistically to produce curative therapeutic effects provided by the whole formula (Kattan, abstract, last sentence). These data show that one cannot simply eliminate components from a complex herbal formulation and expect a comparable level of activity. Likewise, one would not have predicted the efficacy of the claimed compositions based on a reading of Sampson. Sampson fails to provide a motivation to arrive at the compositions of the present claims, or an expectation that they would work. In view of the foregoing, applicants respectfully request withdrawal of the rejection of claims 1-7 and 10-15 under 35 U.S.C. § 103.

Claims 8 and 9 were rejected as unpatentable over Sampson, as applied to claims 1-7 and 10-15, and in further view of the specification. Claims 8 and 9 depend from claim 5, and specify that the composition include an additional agent which is epinephrine or a bronchodilator. The claims are patentable over Sampson for reasons discussed above. The citation of epinephrine and bronchodilators in applicants' own specification does not supplement for the deficiencies of Sampson. Withdrawal of the rejection of claims 8 and 9 is respectfully requested.

Conclusion

Applicants invite the Examiner to contact the undersigned, Margo H. Furman, at (617) 248-4073 with any questions pertaining to the above-identified application in order to expedite prosecution of this case. This Response is being filed with a Petition for Extension of Time and required fee. In the event that any further extensions or fees are required, please consider this a conditional petition and authorization to charge any fees to Deposit Account No. 03-1721, referencing attorney docket no. 2005577-0010.

Respectfully submitted,

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